Title: CSAV/Nacional Space Charter Agreement.

Parties: Compania Sud Americana de Vapores ("CSAV") Companhia Maritima Nacional ("Nacional").

Synopsis: The proposed Agreement permits Nacional to charter space on CSAV's vessels and coordinate sailings in the trade between East Coast ports in South America and U.S. Atlantic Coast ports and points.

Dated: August 28, 1996.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 96-22355 Filed 8-30-96; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 17, 1996.

A. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Raye Plahn Revocable Trust (Trustee is Ms. Raye Plahn), both of Shell Lake, Wisconsin; to retain a total of 10.52 percent of the voting shares of Shell Lake Bancorp, Inc., Shell Lake, Wisconsin, and thereby indirectly acquire Shell Lake State Bank, Shell Lake, Wisconsin.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Joe Dan Coe, Winnsboro, Texas; to retain a total of 14.09 percent of the voting shares of Franklin National Bankshares, Inc., Mt. Vernon, Texas, and thereby indirectly acquire Franklin National Bank, Mt. Vernon, Texas.

Board of Governors of the Federal Reserve System, August 27, 1996.

William W. Wiles

Secretary of the Board.

[FR Doc. 96-22281 Filed 8-30-96; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.-3 p.m., September 19, 1996.

Place: CDC, Auditorium A, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: This committee advises the Director, CDC, on policy issues and broad strategies that will enable CDC, the Nation's prevention agency, to fulfill its mission of promoting health and quality of life by preventing and controlling disease, injury, and disability. The Committee recommends ways to incorporate prevention activities more fully into health care. It also provides guidance to help CDC work more effectively with its various constituents, in both the private and public sectors, to make prevention a practical reality.

Matters to be Discussed: Agenda items will include updates from CDC Director, David Satcher, M.D., Ph.D., followed by committee discussion on strategic thinking about the future of CDC and public health, and on lessons from the Los Angeles measles vaccine study.

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: Linda Kay McGowan, Acting Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D-24, Atlanta, Georgia 30333, telephone 404/639-7080.

Dated: August 27, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-22333 Filed 8-30-96; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 96E-0102]

Determination of Regulatory Review Period for Purposes of Patent Extension; CEDAX® Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CEDAX® capsules and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be

subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CEDAX® capsules (ceftibuten dihydrate). CEDAX® capsules is indicated for the treatment of individuals with mild-to-moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions: Acute Bacterial Exacerbations of Chronic Bronchitis due to *Haemophilus influenzae* (including B-lactamase-producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptoccocus pneumoniae* (penicillin-susceptible strains only), Acute Bacterial Otitis Media due to *H. influenzae* (including B-lactamase producing strains), *M. catarrhalis* (including B-lactamase producing strains), or *S. pyogenes*, or Pharyngitis and Tonsillitis due to *S. pyogenes*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CEDAX® capsules (U.S. Patent No. 4, 634,697) from Schering-Plough Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CEDAX® capsules represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CEDAX® capsules is 3,065 days. Of this time, 1,603 days occurred during the testing phase of the regulatory review period, while 1,462 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: August 1, 1987. The applicant claims August 2, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: December 20, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for CEDAX® capsules (NDA 20-685) was initially submitted on December 20, 1991.

3. *The date the application was approved*: December 20, 1995. FDA has verified the applicant's claim that NDA 20-685 was approved on December 20, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term restoration.

Anyone with knowledge that any of the dates as published is incorrect may, on or before November 4, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before March 3, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 16, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96-22285 Filed 8-30-96; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

[BPD-842-NC]

RIN 0938-AH70

Medicare Program; Schedule of Prospectively Determined Payment Rates for Skilled Nursing Facility Inpatient Routine Service Costs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice with comment period.

SUMMARY: This final notice with comment period sets forth the schedule of payment rates for low Medicare volume skilled nursing facilities for prospective payments for routine service costs for Federal fiscal year 1997 (cost reporting periods beginning on or after October 1, 1996 and before October 1, 1997). Section 1888(d) of the Social Security Act requires the Secretary to establish and publish the prospectively determined payment rates 90 days prior to the beginning of the affected Federal fiscal year.

DATES: Effective date: The schedule of payment rates is effective for cost reporting periods beginning on or after October 1, 1996.

Comment date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on November 4, 1996.

ADDRESSES: Mail written comments (an original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-842-NC, P.O. Box 7517, Baltimore, MD 21244-0517.

If you prefer, you may deliver your written comments (an original and three copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: BPD-842-NC@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address, below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In